Latest News Update

ALERT: CHANGES IN PRESCRIBING HYDROCODONE COMBINATION DRUGS
October 1, 2014

Effective October 6, 2014, the DEA has reclassified hydrocodone combination drugs from Schedule III to Schedule II. This, along with several concurrent state law changes already in effect, will have significant effects on many physician practices.

1. How will the change in hydrocodone combination drug classification affect my practice?

Hydrocodone itself has always been listed as Schedule II. Hydrocodone in combination with other active non-narcotic ingredients, however, was previously designated as the less tightly-regulated Schedule III. The decision to make the change in classification was made by the FDA after a six-year HHS analysis based on a high level of hydrocodone combination drug diversion and the health hazards they consequently posed.

Because 25 percent of all controlled substance prescriptions written in Louisiana are for hydrocodone combination drugs, most physician practices that prescribe controlled substances will experience an increase in the administrative burden of prescribing these common drugs.

The least well known and most inconvenient change is found in a Louisiana law already in effect. Starting August 1, 2014, a prescriber must access (or query) the Louisiana Prescription Monitoring Program (PMP) before first prescribing any Schedule II drug to a new patient. The law applies to patients being treated for non-cancer related chronic or intractable pain. In summary, intractable pain is defined by the Louisiana State Board of Medical Examiners as: a chronic pain in which the pain's cause cannot be eliminated or successfully treated without a controlled substance, and no cure of the cause of pain is possible or no cure has been achieved after reasonable efforts.

Plainly, this query to the Louisiana Prescription Monitoring Program imposes a significant burden because it must be done concurrently, as the prescription is written, before the patient leaves the prescriber's office. Until very recently, only the prescriber of a controlled drug was authorized to register and query the PMP. In order to somewhat relieve this administrative burden, the Louisiana Board of Pharmacy has authorized a mechanism which allows the prescriber to designate a staff member to make the query. The prescriber must first register and link the delegate's PMP account to the prescriber's account.

Second, the plain language of this new Louisiana PMP rule requires a query for any new Schedule II prescription, even if the patient had previously been using the hydrocodone combination medication prescribed by a previous healthcare providers. As a rule of thumb, if this is the first time you are prescribing the Schedule II drug for this patient, you must make the PMP query. As a good risk management practice, the prescriber should document the need for the Schedule II drug prescription at the time of the first prescription, using, if clinically indicated, language that is similar to the statutory definition of chronic intractable pain.

2. Does this change the way I will write the hydrocodone combination drug prescriptions my patients need?

Yes. Scheduled II drugs cannot be refilled, and will require a new prescription each month. Effective August 1, 2014, a newly enacted Louisiana law provided that no Schedule II drug prescriptions may be filled more than 90 days after the date on the prescription (meaning the

date the prescription was actually written). Many healthcare practitioners expressed concern that the change in the hydrocodone combination drug schedule may cause patients to return more frequently for prescription refills. The Drug Enforcement Agency (DEA) addressed this concern.

Under federal law, a practitioner may write multiple Schedule II prescriptions in order to provide a 90-day supply. Louisiana law also allows a practitioner to write multiple Schedule II prescriptions at one time, for up to a 90-day supply, provided that the practitioner places written instructions on each prescription (not just the first one) indicating the earliest date the prescription may be dispensed. However, the DEA explicitly stated that it does not impose a specific qualitative minimum or maximum limit on the amount of medication that can be prescribed on a single prescription, or the duration of the treatment intended with the prescription.

3. Will hydrocodone combination drug refills written before October 6, 2014 remain eligible for refills after October 6?

Prescriptions for hydrocodone combination drugs that are issued before October 6, 2014, and thus authorized for refilling as a Schedule III drug, should still be eligible for refill up until April 8, 2015. However, sources indicate that other reimbursement and technical factors may prevent these refills. Some pharmacies are reporting that they cannot make the required quality, safety and computer systems changes in time to comply. Additionally, there are reports that some health insurers will not pay for these types of refills.

In general, in October be prepared to receive numerous phone calls and requests that prescriptions for hydrocodone combination drugs be re-written.

For more information and help to comply with these new rules:

LAMMICO Risk Management and Patient Safety Department at (504) 841-5211 or riskmanagement@lammico.com

Louisiana Board of Pharmacy contact Joe Fontenot, R.PH. (225) 925-4767, dclausen@pharmacy.la.gov, info@pharmacy.la

Louisiana Prescription Monitoring Program Guidebook and Technical Manual

Louisiana Board of Pharmacy September 8, 2014 memo concerning how to register for the PMP web-based system that enables Louisiana prescribers and dispensers to access their patients' controlled substance prescription history

Louisiana Board of Pharmacy September 22, 2014 memo concerning how to register a delegate to access the PMP program.

DEA answers FAQ on rescheduling of hydrocodone products, https://www.federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule#h-4

Louisiana Administrative Code, Title 46, Part XLV, Subchapter B, Medical Professional and Occupational Standards, §6915.Pg 197-198 for Medications Used in the Treatment of Non-Cancer-Related Chronic or Intractable Pain

La. Admin Code. Title 46, pt. LIII, § 2745(b) Refilling of Prescriptions; Issuance of Multiple Prescriptions

Louisiana Administrative Code, Title 40 Part X. Uniform Controlled Dangerous Substances Law (includes a list of Controlled Substances). For August 1, 2014 new laws, see §978 (A-F). Prescriptions